(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 December 2003 (24.12.2003)

PCT

(10) International Publication Number
WO 03/105703 A2

(51) International Patent Classification[7]: A61B 17/08

(21) International Application Number: PCT/US03/18753

(22) International Filing Date: 12 June 2003 (12.06.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/170,530 12 June 2002 (12.06.2002) US

(71) Applicant *(for all designated States except US)*: **COAPT SYSTEMS, INC.** [US/US]; 1820 Embarcadero Road, Palo Alto, CA 94303 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **JACOBS, Daniel** [US/US]; 4289 Brianwood Way, Palo Alto, CA 94306 (US). **ELSON, Robert, J.** [US/US]; 14370 Miranda Road, Los Altos Hills, CA 94022 (US). **PAGANELLI, Jude, V.** [US/US]; 70 Berens Drive, Kentfield, CA 94904 (US).

(74) Agents: **HAN, Johney, U.** et al.; Morrison & Foerster, LLP, 755 Page Mill Road, Palo Alto, CA 94304 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BR, BY, BZ, CA, CH, CN, CO, CR, CU, DE, DK, DM, DZ, EC, ES, FI, GB, GD, GE, GH, GM, HR, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RU, SC, SD, SE, SG, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 03/105703 A2

(54) Title: MULTI-POINT TENSION DISTRIBUTION SYSTEM DEVICE AND METHOD OF TISSUE APPROXIMATION USING THAT DEVICE TO IMPROVE WOUND HEALING

(57) **Abstract:** A tissue approximation device and processes for using the device are provided. The device is an implantable, biodegradable constr uct (except for hernia repairs) that has attachment points emanating from a supportive backing. The device improves the mechanical phase of wound healing and evenly distributes tension over the contact area between the device and tissue. Processes for using the device include wound closure, vascular anastomoses, soft tissue attachment and soft tissue to bone attachment.

MULTI-POINT TENSION DISTRIBUTION SYSTEM DEVICE AND METHOD OF TISSUE APPROXIMATION USING THAT DEVICE TO IMPROVE WOUND HEALING

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This is a continuation-in-part of U.S. Patent Application Serial Number 09/574,603 entitled "Multi-Point Tension Distribution System Device And Method Of Tissue Approximation Using That Device To Improve Wound Healing" filed May 19, 2000, now pending and incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] This invention is in the field of surgery. More particularly, it relates to a tissue approximation device that facilitates wound healing by holding soft tissue together under improved distribution of tension and with minimal disruption of the wound interface and its nutrient supplies. The device has multiple sites for grasping said tissue using tines or prongs or other generally sharp, projecting points, extending from a single, supportive backing. Various processes of using the inventive device are also a portion of the invention.

BACKGROUND OF THE INVENTION

[0003] The surgically induced healing of soft tissue wounds involves two phases, the mechanical phase of wound closure followed by the biochemical phase which involves protein bridging and scarring. In the mechanical phase, the edges of soft tissue are held in contact by essentially two components: 1) The physical properties and device-tissue

same surgeon, result in a significant component of sub-optimal technique. Yet, the technique used for wound closure forms the foundation for all subsequent events in the healing process. It is during this mechanical phase that tissue tension is high, edema and inflammation are intense, wound edge ischemia is greatest, and that one can already observe the complication of wound failure.

[0008] Soft tissue is well known for its inability to hold tension. Even when optimally placed, sutures gradually tear through soft tissue, producing gaps in wounds and possibly leading to the eventual failure or sub-optimization of wound healing. Furthermore, since sutures require the implementation of high levels of tension to counteract the forces acting to separate tissues, they may strangulate the blood supply of the tissues through which they are placed, thus inhibiting the delivery of wound nutrients and oxygen necessary for healing.

[0009] There have been many attempts to construct wound closure devices that decrease closure time and improve cosmesis. U.S. Pat. Nos. 2,421,193 and 2,472,009 to Gardner; 4,430,998 to Harvey et al.; 4,535,772 to Sheehan; 4,865,026 to Barrett; 5,179,964 to Cook; and 5,531,760 to Alwafaie suggest such devices. However, these devices are not useful in surgical or deeper wounds. They only approximate the skin surface, joining skin edges variously through external approaches, using adhesives or nonabsorbable attachment points that penetrate tissue. The devices minimally improve the biomechanics of wound closure, and do not adequately approximate the deeper layers of the closure, i.e. fascia or dermis. Externally placed attachment points that puncture the skin lateral to the wound also interfere with long-term cosmesis and provide a possible conduit for infecting micro-organisms.

SUMMARY OF THE INVENTION

[0013] The present invention is a device that improves the mechanical phase of wound healing. In the preferred embodiment, tissue edges are stabilized by a plurality of attachment points that extend from a supportive backing. The density, shape, length, and orientation of attachment points on the backing may be varied to suit the procedure, type of tissue being approximated, and/or area of the body involved. Moreover, various types of coatings may be selectively placed over the device to effect various responses. The flexibility of the backing is also variable and dependent on the materials used and dimensions of the backing. In the preferred embodiment, the device is biodegradable, and the attachment points uniformly distribute tension over the contact area between the device and tissue.

[0014] Processes of using the present invention are also provided. The device may be used to close wounds and create vascular anastomoses. The device may also be manipulated to approximate soft tissue and soft tissue to bone.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] Figures 1A-1D are plan, perspective views of various MTDS devices.

[0016] Figures 1E-1G are plan, perspective views of a MTDS device which may have various portions broken off to create a custom fitted device.

[0017] Figures 1H-1K are plan, perspective views of another variation on the MTDS device which may also have various portions broken off to create a custom fitted device.

[0031] Figures 6A-6B are schematic views of a skin wound and wound repair using the MTDS device.

[0032] Figure 7 is a schematic view of an abdominal wound closure using MTDS devices.

[0033] Figures 8A-8B are schematic views of an abdominal hernia and hernia repair using the MTDS device.

[0034] Figures 8C-8D are side and schematic views, respectively, of a MTDS device with attachment points on the edges of the backing and a central area without attachment points.

[0035] Figures 9A-9B are schematic views of a ruptured tendon and tendon to bone repair using the MTDS device.

[0036] Figure 10A is an axial view of a cross-section of a vessel repaired with the MTDS device.

[0037] Figures 10B-10C are side, schematic views of vessel free ends and a vascular anastomosis using the MTDS device.

[0038] Figures 11A and 11B-11C are schematic, side, and cross-sectional side views, respectively, of a transected tendon and a tendon to tendon repair using the MTDS device.

[0039] Figure 11D is an axial, cross-sectional view of the MTDS tendon to tendon repair.

[0040] Figure 11E is a side view of a vascular anastomosis using the MTDS device on the external surface of a vessel.

example, a tightly curved or mobile part of the body, e.g. a joint, will require a more flexible backing, as would a tendon or nerve repair due to the amount of bending the device needs for the attachment. Also, depending on the type of material used, the thickness of the backing as well as its width and length may determine the flexibility of the device. Furthermore, the backing may be pre-fabricated into different shapes as shown by the sharp corners (104) and rounded corners (106) in Figures 1C and 1D. The fabricated cross-sectional shape and dimensions of the mesh elements may vary to promote flexibility in regions of the backing. The cross-sectional shape of the mesh elements may be chosen to minimize local compressive stress between the backing and surface it rests upon, or have rounded and filleted edges to be less obtrusive to local circulation. The plurality of attachment points distribute tension over the contact area between the device and the tissue.

[0049] Figures 1E to 1G show variations of the device in which the backing (100) may be pre-fabricated into a standard shape with serrations or score lines (108) formed throughout the backing (100). Serrations (108) may be formed by scoring the backing (100) to create regions or boundaries having a reduced cross-sectional area relative to other parts of the backing (100). These serrations (108) may then allow a physician or surgeon to selectively break off portions of the backing (100) to create a device which is custom fitted for placement within specific regions of the body. Figure E shows one variation in which backing (100) has serrations (108) formed at regular intervals over the device. Prior to placement within the body, the physician may break off part of the backing (100) along break line (110), as shown in Figure 1F, to form a device having a reduced area. Alternatively, as shown in Figure 1G, the device of Figure 1E may be selectively broken along break lines (112) for forming a device having a diamond shaped backing.

material. The inflammatory response to these polymers is minimal, and they have been safely used in suture materials, stents, drug delivery devices, orthopedic fixation devices, and intestinal anastomotic rings.

[0052] Generally, we will refer to the attachment points as "tines" or "prongs". These tines will refer both to points which are either sharp, i.e. able to separate tissue in a chosen use, or blunt, i.e. not able to separate tissue in that use. The attachment points may also be referred to as "barbs" when those points have the retaining point shown in several of the Figures discussed below.

[0053] As shown in Figures 2A-2E, the shape of the attachment points or barbs may be varied depending, e.g., on the area of the body involved and the type of tissue requiring closure or reapproximation. The tines may be canted or erect, but in a preferred variation, the general structure of the tines is of a rose thorn shape. The tines (200) have a wide base (202) that supports a projection (204) from the backing (206) against the degree of tension required to close a wound or approximate tissue. For example, the attachment points may be erect tine (Fig. 2B-208), canted tine (Fig. 2C-210), canted arrowhead (Fig. 2D-212), canted hook (Fig. 2E-214), or may have a single straight cross-section (Fig. 3G-311) that is nail-like, that does not vary over the length of the prong, for example, similar in shape to a nail or sharpened pencil. Furthermore, the tip of the attachment points may be varied as shown in Figures 3A-3D. The tips may be barbed (300), arrowhead (double-barb) (302), or cheese grater (304). A side view of the cheese grater tips is shown in Figure 3D.

[0054] The connection of the prong to the backing may be rounded or filleted, or the backing built-up around the prong, to reduce structural stress concentrations. The backing or connecting structure may branch out away from the center, with each branch in

as the attachment points which are then secured to a backing (410). The backing may also be comprised of a solid material (412) instead of a porous material.

[0057] The extent of porosity, or total surface area may be used to control the absorption rate of the device, and may also be used to optimize the strength-to-mass properties of the device, increasing the section modulus of structural cross-sections per unit mass. The backing structure may comprise partial folds, waves or grooves to help hold tissue against both surfaces of the backing. Regions of the backing may function as suction cups to help hold tissue to the backing.

[0058] The density, distribution, length, and orientation of attachment points on the backing may be modified depending on the type of wound closure. Attachment points may be bent or curve gradually, with the tip directed at an optimal angle relative to the backing to aid device penetration and stability within the tissue, and to reduce tissue irritation after device installation. Attachment points may be canted in one direction (500), such as toward the center of the device as shown in Figure 5A. The attachment points may also be variously oriented, such as toward center (502) and erect (504), or toward center (502) and away from center (506). It is within the scope of this invention to have attachment points extending in any relative direction or orientation on the backing. Or, as shown in Figure 5D, the backing is divided into a first area (508) and a second area (510). Attachment points in the first area (512) and second area (514) are canted toward each other. The inventive device may also be sectioned into a plurality of areas, with each section being variously oriented to another section.

[0059] In another variation of the invention, attachment points of various lengths emanate from a single backing. For example, in Figure 5E, the attachment points (515) are

device to the tissue or bone surface, another type may be used to encourage or enhance the growth of the bone upon or within which the device is placed, e.g., bone matrix protein. Various coatings may also be used to create a lubricious surface over the device to facilitate its insertion within the tissue or bone. Another type of coating made from, e.g., fibroblast growth factors, may be used to enhance the healing of the wound or a coating made with, e.g., lidocaine, may also be an analgesic to reduce any accompanying pain. Another type of coating may be used on the device to promote the biocompatibility of the device and to reduce the risk of rejection by the body. To enhance the healing of the wound as well as to promote the biocompatibility of the device, the coating made from, e.g., aminoglycoside, may additionally have anti-viral and anti-bacterial properties.

[0062] Alternatively, other coating variations made from, e.g., corticosteroids, may be used to prevent or manipulate, i.e., minimize, any resulting scars, accelerate degradation of the underlying backing, or alternatively to enhance the structural strength of the device, i.e., materials such as linear polymers which increase the tensile strength of the device. Moreover, another coating variation having a high surface roughness may be coated over the device to provide an increased roughened area for facilitating tissue and bone ingrowth as well as helping to prevent slippage of the device. Any of the preceding coatings which may be utilized may include any types of coating materials as conventionally known and used in the art.

[0063] Portions of simple wound closures are shown in Figures 6A-6B. These wound closures involve placing the MTDS device (600) at the bottom of the wound, usually at the level of the sub-dermis (602). The edges of the wound (604) are approximated and then secured by fixation, e.g., by pressing, to the multiple attachment

mechanical fixation of the tissues, the biochemical phase of the wound healing process will begin, eventually forming a natural union between tendon and bone. Ligament and cartilage to bone unions using the MTDS device would undergo the same mechanical and biochemical processes.

[0066] Vascular anastomoses may also be constructed with the MTDS device. In Figure 10B, the backing has a tubular shape (1000) with attachment points (1001) on the outside surface (1002). The outside surface (1002) has a first end (1003) and a second end (1005) that opposes the first end (1003). The free ends of a vessel(s) (1004) are placed over the device, creating an anastomosis (1006) that is secured by attachment points fixed into the wall of the vessels (1008). The attachment points are preferably pointing towards the anastomosis (1006), with the attachment points on the first end (1003) being canted toward the second end (1005) and vice-versa. An axial view of the relationship of the attachment points (1010) to the vessel wall (1012) is shown in Figure 10A.

[0067] Vessels and other soft tissue such as nerves, cartilage, tendons, and ligaments may also be joined as seen in Figures 11A and 11B. Two ends of tissue (1100) are brought and held together by the backing and attachment point construct (1102) being wrapped around the circumference of the tissue (1104). The attachment points (1106) are on the inside surface of the backing (1107) and secure the union at a central region (1108) as seen in Figure 11C. An axial, cross-sectional view of the relationship between the attachment points (1110) and tissue (1112) is shown in Figure 11D. The resulting form is, i.e., a tubular structure that has an inside surface (1107) with a central region (1108). The attachment points on the inside surface (1106) are canted toward the central region (1108). Figure 11E shows the device with attachment points (1101) on the inside surface of the

the backing (1120) formed into two semi-circular halves. To prevent the device from slipping off the tubular structure (1115), an optional locking mechanism (1136) may be placed at or along the edges of the device such that the mechanism (1136) is able to lock to itself when wrapped about a tubular structure (1115). Such a locking mechanism (1136) may include any number of conventional mechanical fasteners, e.g., clasps, hooks, keyed edges, screws, biocompatible adhesives, etc.

[0070] The MTDS device may also be used in soft-tissue remodeling, such as a brow-lift, shown in Figure 12A. After dissection of the scalp (1200), the anterior scalp flap (1202) may be raised over the attachment points (1204) to lift the brow (1206). The ends of both the anterior flap (1202) and posterior flap (1208) may then be trimmed and fixed onto the attachment points (1204) to close the wound. The device may be secured to the skull (1210) by a screw (1212). Alternatively, the device may be secured to the skull by a post (1220) rather than a screw (1212). The post (1220) may be comprised of a bioabsorbable material, as described above, or it may be made of a biocompatible metal or alloy, e.g., stainless steel. The outer surface may be non-threaded and smooth or it may define grooves or projections thereon to aid in maintaining the post (1220) within the skull. In either case, post (1220) may be inserted within the skull and held in place via friction fitting or interference fitting where the diameter of the hole within the skull is slightly smaller than the overall diameter of the post (1220). The post (1220) may also have a cross-sectional shape or area which is non-uniform along its length. For instance, the post cross-section may decrease or alternatively increase along its length. It may also have a reduced or enlarged cross-sectional shape or area near the central portion of the post. Moreover, although a single post (1220) is shown in the figure, any number of anchors may

CLAIMS

I CLAIM AS MY INVENTION:

1. An implantable device for placement on a tissue surface and interior to an exterior tissue surface comprising:

a) a biodegradable supportive backing which defines at least one serrated boundary thereon, the backing having:

i.) at least a first area with a plurality of biodegradable attachment points extending from the first area for attaching to a selected tissue and

ii.) a second area discrete from the first area,

wherein the backing has physical characteristics sufficient to approximate or to support the selected tissue adjacent the first area with respect to the second area, and

b) the plurality of biodegradable attachment points extending from the first area, wherein the plurality of biodegradable attachment points are configured to attach to the selected tissue and to distribute tension between the first area and the selected tissue.

2. The implantable device of claim 1 wherein the supportive backing is adapted to separate along the serrated boundary.

3. The implantable device of claim 1 wherein the supportive backing further defines a plurality of serrated boundaries thereon.

4. The implantable device of claim 3 wherein at least one of the plurality of serrated boundaries is defined diagonally relative to the remaining boundaries.

5. The implantable device of claim 1 further comprising a locking mechanism attached to or near at least a first edge of the backing, wherein the locking mechanism is adapted to couple to a second edge of the backing and engagingly hold the first and second edges to one another.

11. The implantable device of claim 10 wherein the coating selectively covers at least a single surface of the supportive backing.

12. The implantable device of claim 10 wherein the coating selectively covers at least one of the biodegradable attachment points.

13. The implantable device of claim 10 wherein the coating comprises an adhesive material adapted to increase adhesion between the implantable device and the tissue surface.

14. The implantable device of claim 10 wherein the coating comprises a material adapted to encourage bone growth.

15. The implantable device of claim 10 wherein the coating comprises a lubricious material.

16. The implantable device of claim 10 wherein the coating comprises a material adapted to enhance healing of the selected tissue.

17. The implantable device of claim 16 wherein the material is further adapted to have anti-viral and anti-bacterial properties.

18. The implantable device of claim 10 wherein the coating comprises an analgesic material.

19. The implantable device of claim 10 wherein the coating comprises a material adapted to promote biocompatibility of the implantable device.

20. The implantable device of claim 19 wherein the material is further adapted to have anti-viral and anti-bacterial properties.

27. The implantable device of claim 24 wherein the supportive backing forms at least two semi-circular halves adapted to bend about the hinge region.

28. The implantable device of claim 24 wherein the locking mechanism is selected from the group consisting of clasps, hooks, keyed edges, screws, and biocompatible adhesives.

29. An implantable device for placement on a tissue surface and interior to an exterior tissue surface comprising:

a) a biodegradable supportive backing having:

i.) at least a first area with a plurality of biodegradable attachment points extending from the first area for attaching to a selected tissue and

ii.) a second area discrete from the first area,

wherein the backing has physical characteristics sufficient to approximate or to support the selected tissue adjacent the first area with respect to the second area, and

b) the plurality of biodegradable attachment points extending from the first area, wherein the plurality of biodegradable attachment points are configured to attach to the selected tissue and to distribute tension between the first area and the selected tissue, and

c) at least one anchoring member defined on the supportive backing and adapted to hold the supportive backing to the tissue surface.

30. The implantable device of claim 29 wherein the anchoring member comprises a screw.

31. The implantable device of claim 29 wherein the anchoring member comprises a post.

32. The implantable device of claim 31 wherein the post has a smooth outer surface.

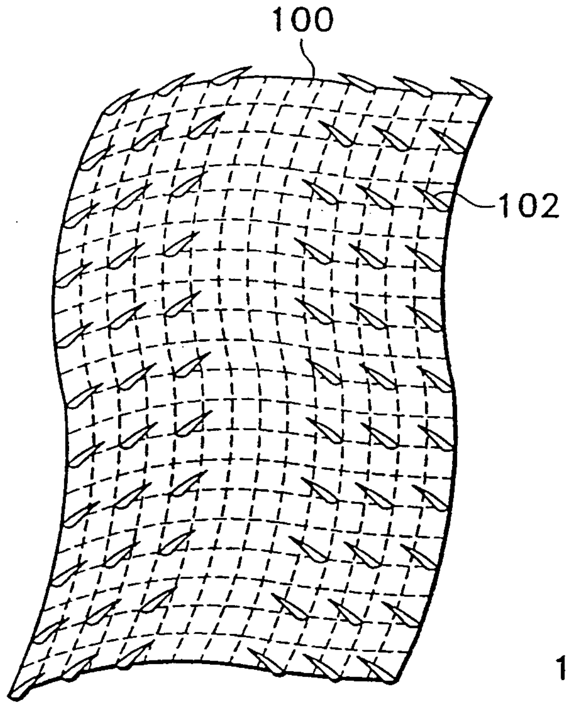


FIG. 1A

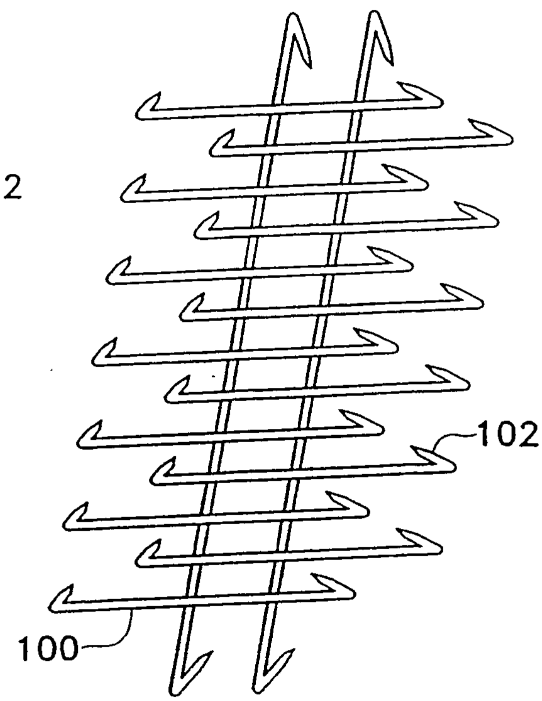


FIG. 1B

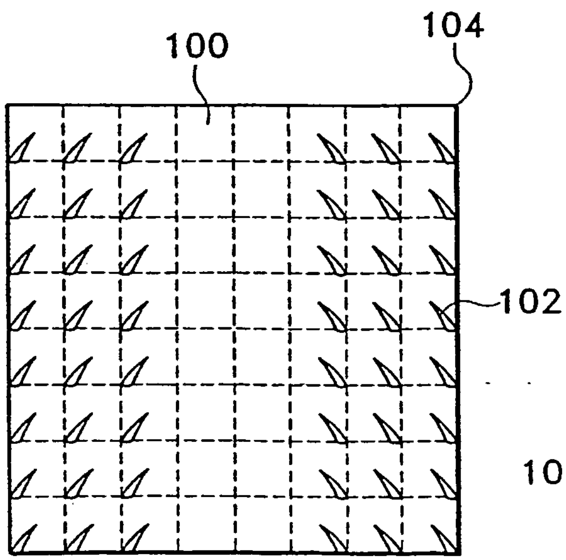


FIG. 1C

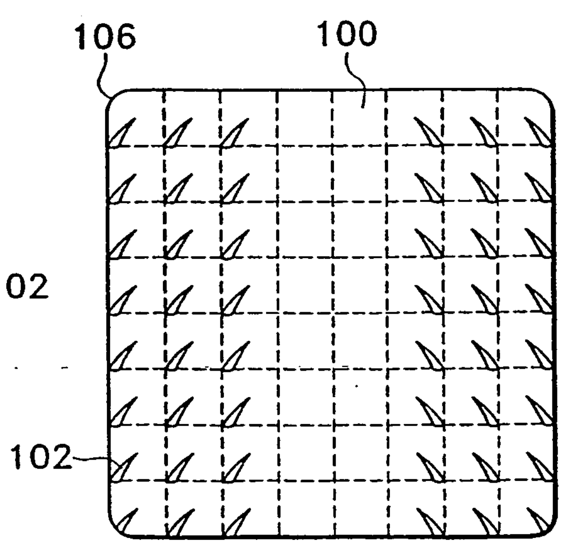


FIG. 1D

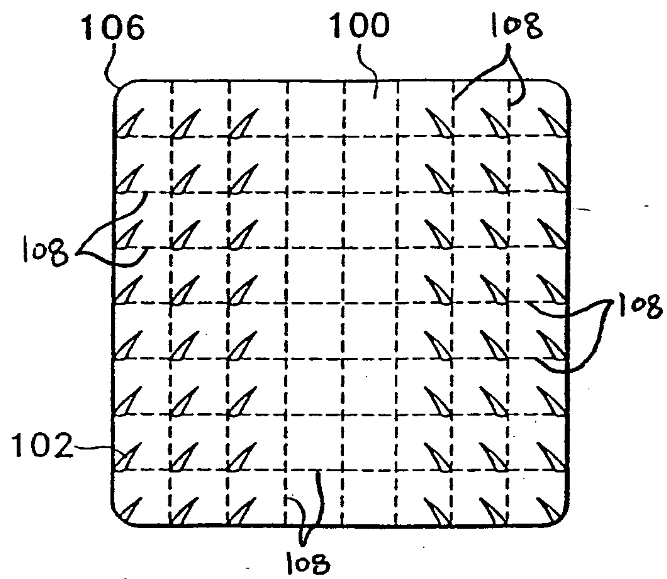


FIG. 1E

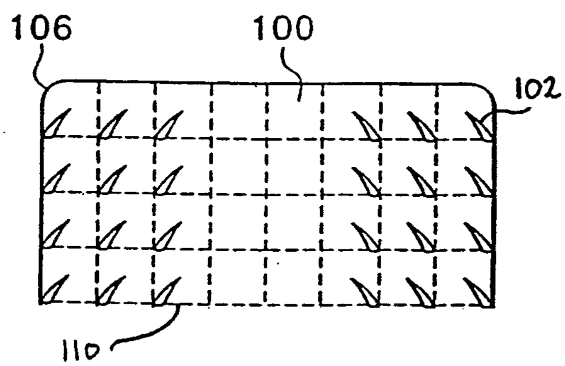


FIG. 1F

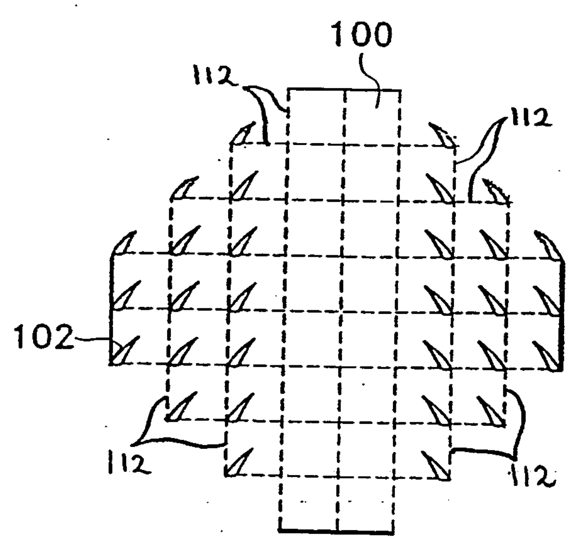


FIG. 1G

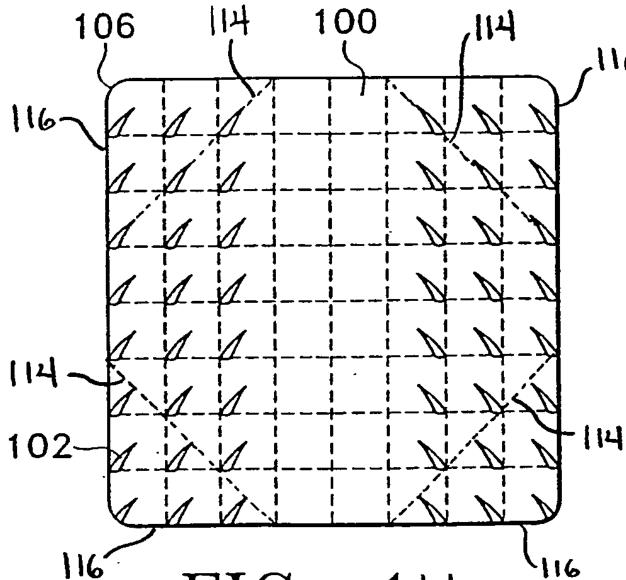


FIG. 1H

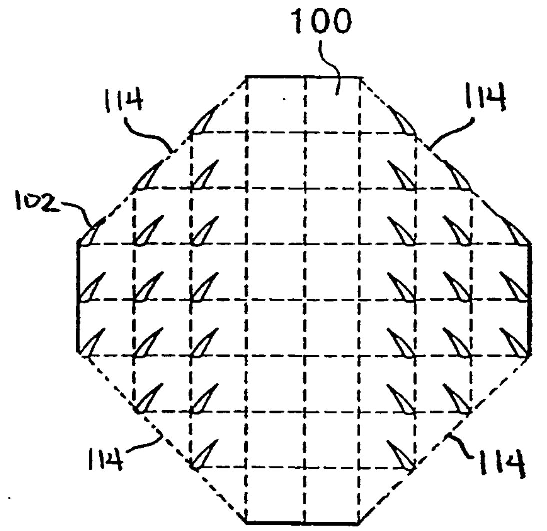


FIG. 1I

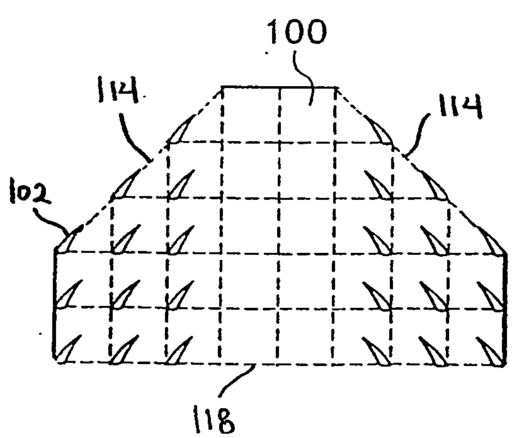


FIG. 1J

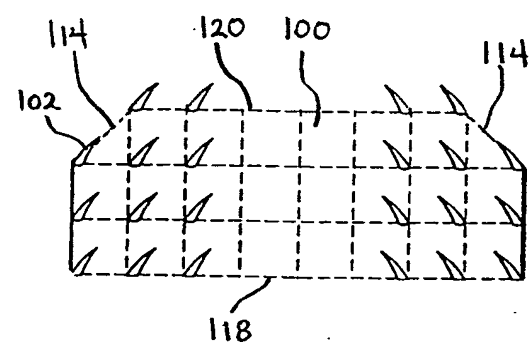


FIG. 1K

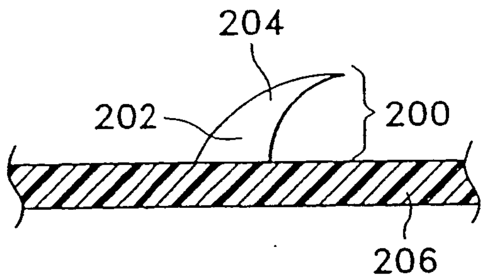


FIG. 2A

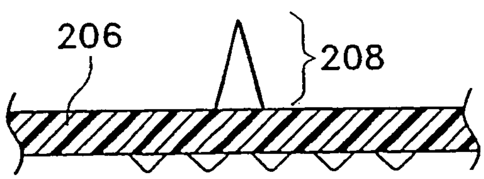


FIG. 2B

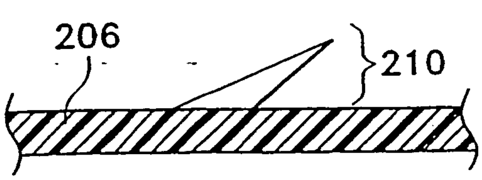


FIG. 2C

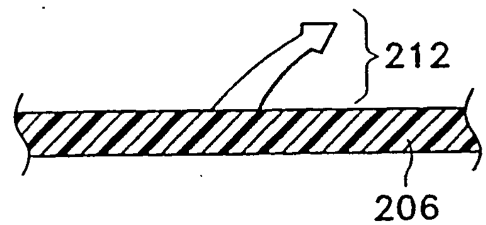


FIG. 2D

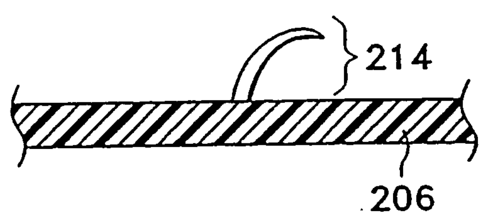


FIG. 2E

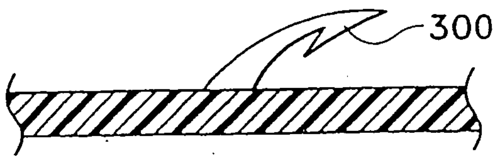


FIG. 3A

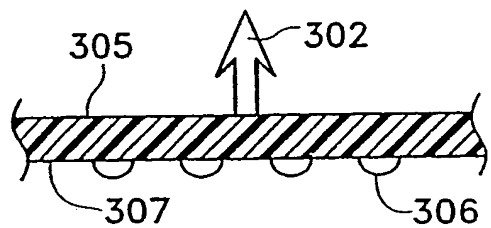


FIG. 3B

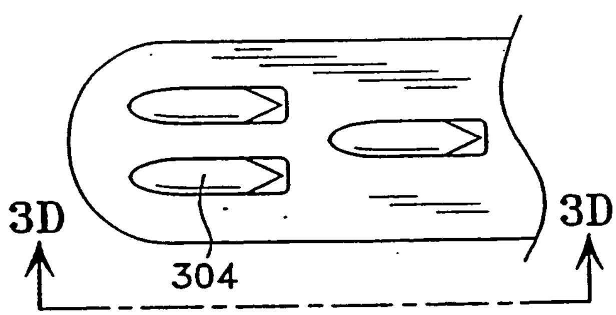


FIG. 3C

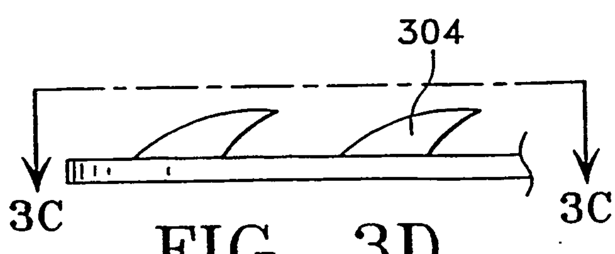


FIG. 3D

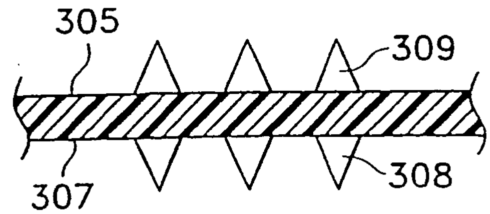


FIG. 3E

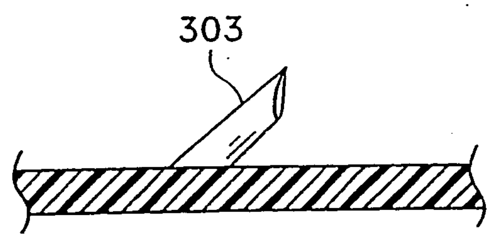


FIG. 3F

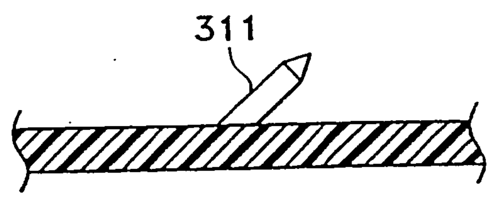


FIG. 3G

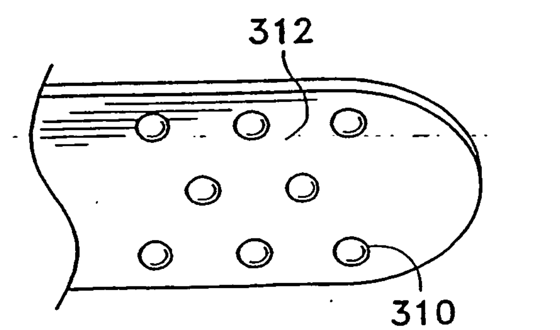


FIG. 3H

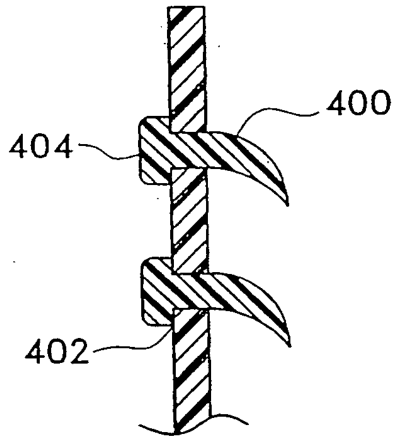


FIG. 4A

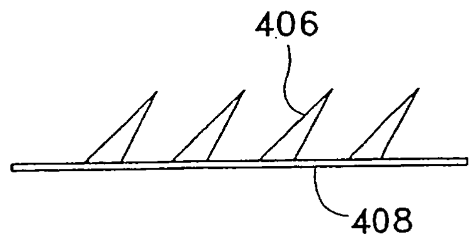


FIG. 4B

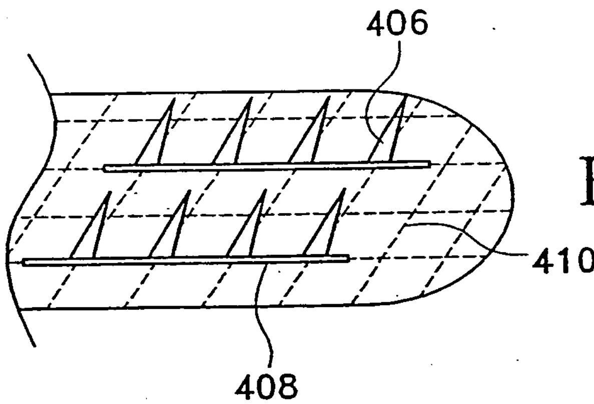


FIG. 4C

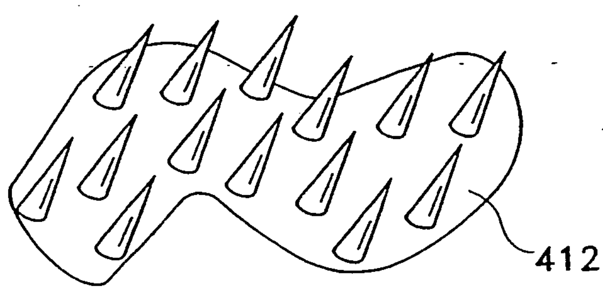


FIG. 4D

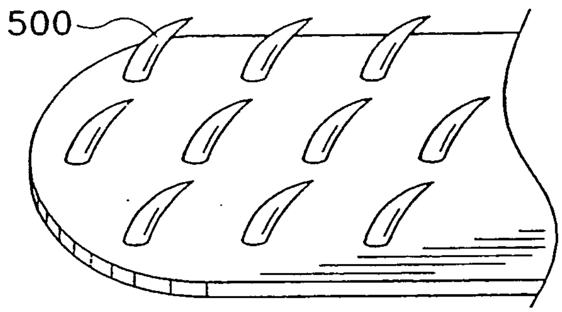


FIG. 5A

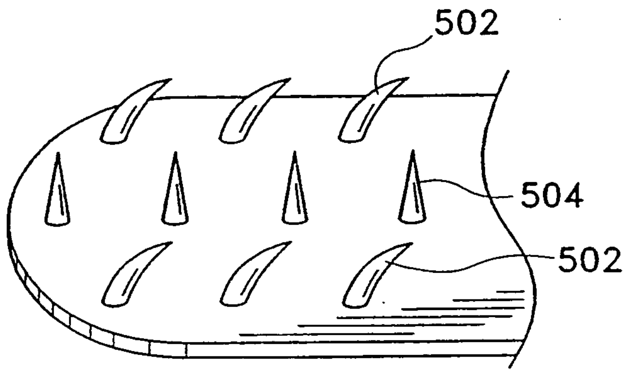


FIG. 5B

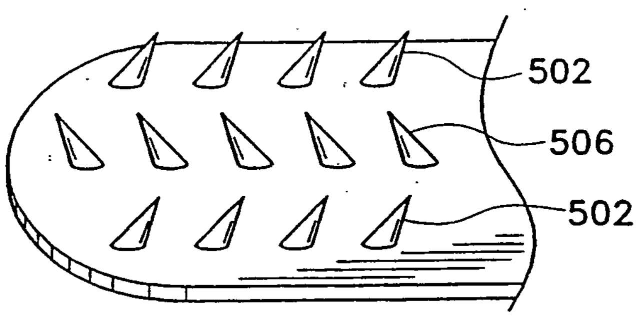


FIG. 5C

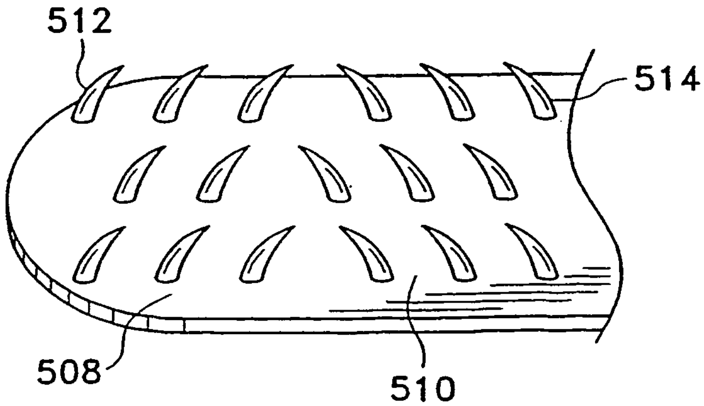


FIG. 5D

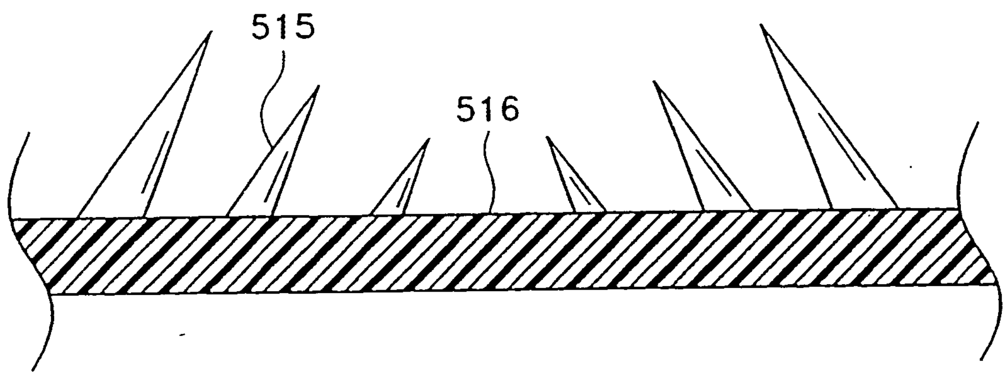


FIG. 5E

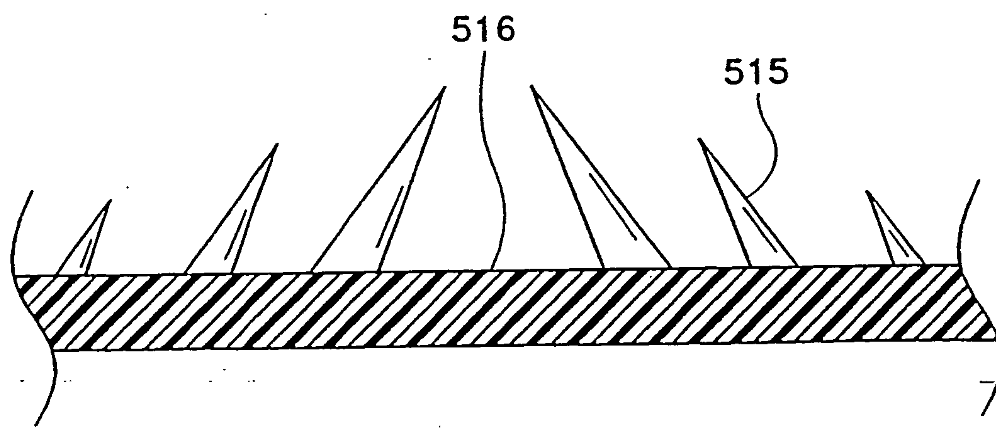


FIG. 5F

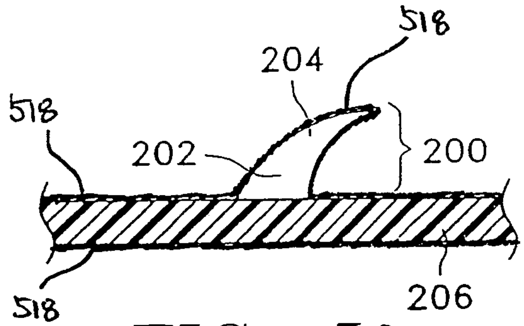


FIG. 5G

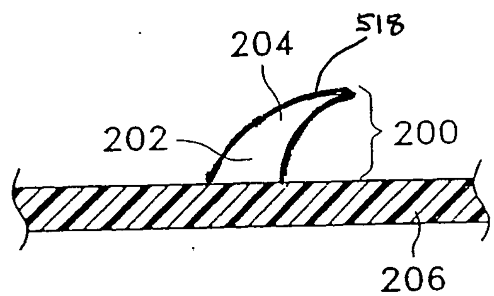


FIG. 5H

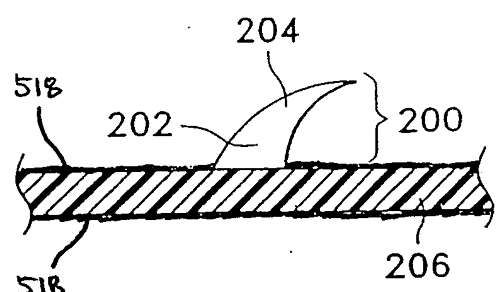


FIG. 5I

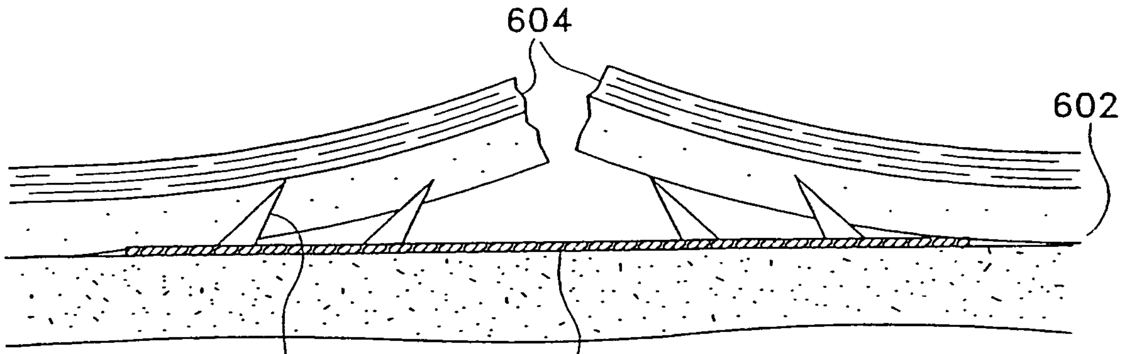


FIG. 6A

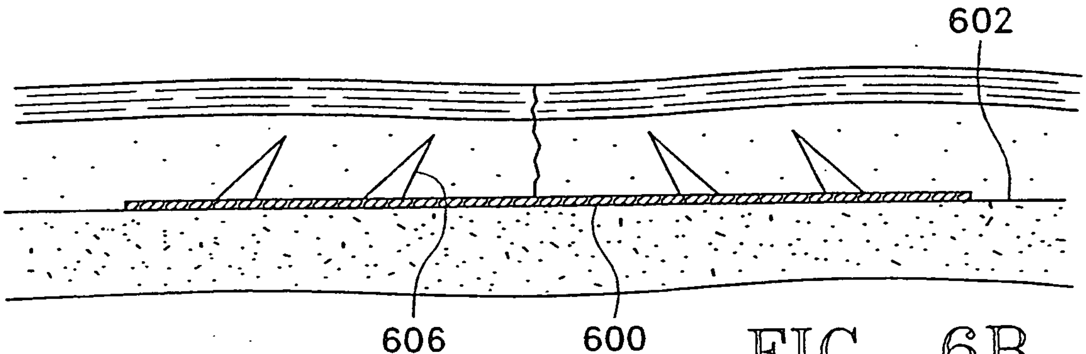


FIG. 6B

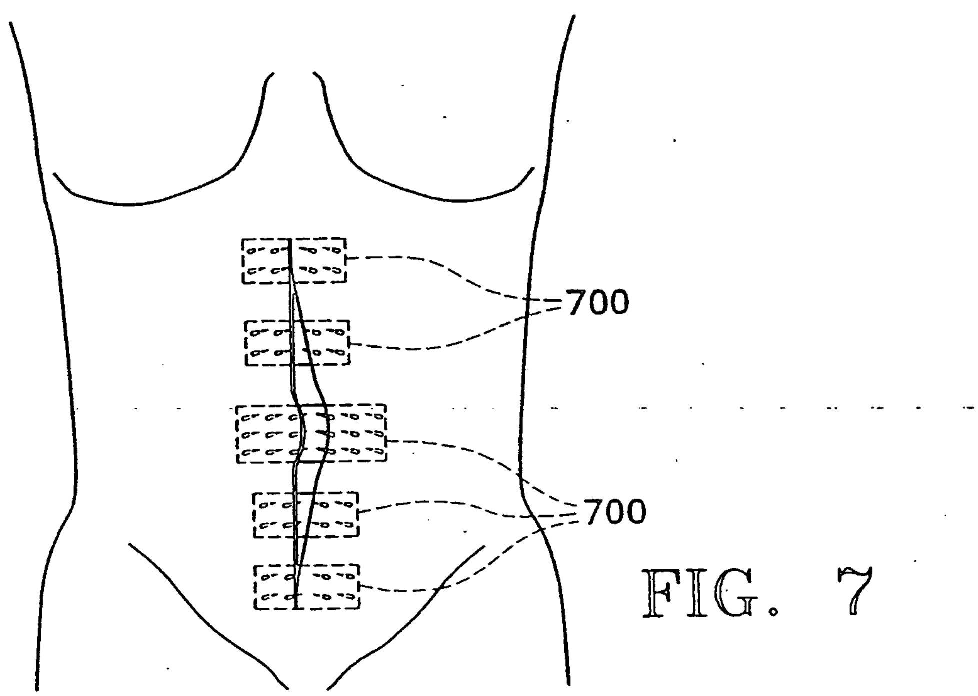


FIG. 7

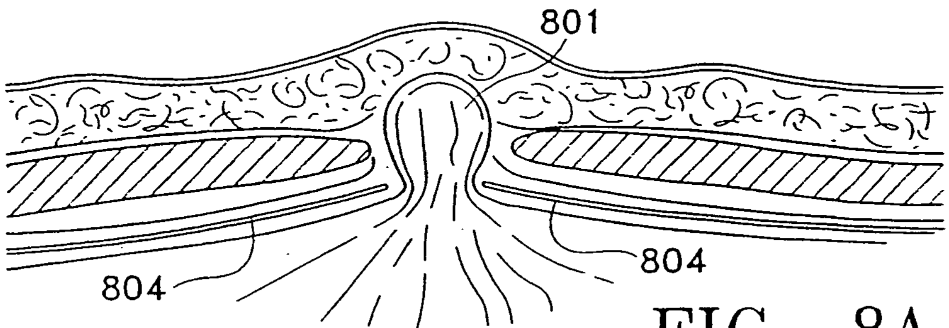


FIG. 8A

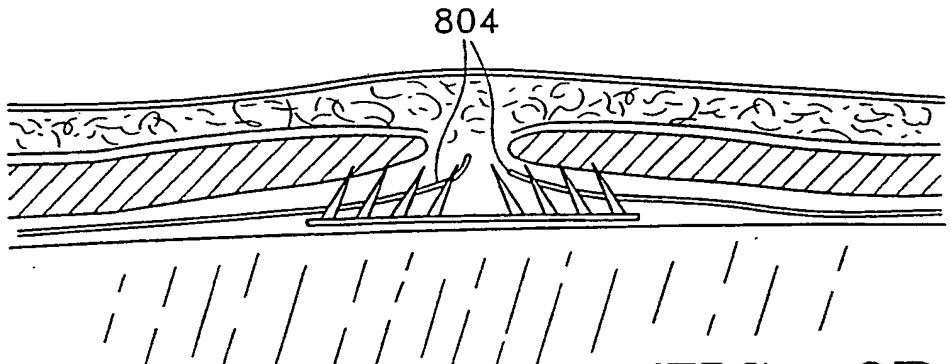


FIG. 8B

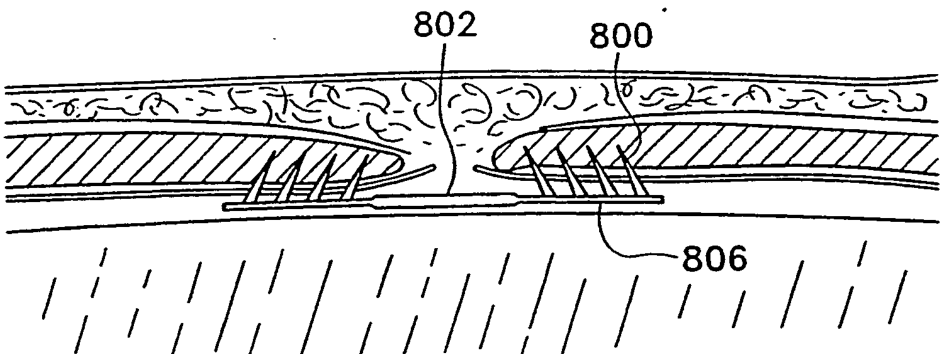


FIG. 8C

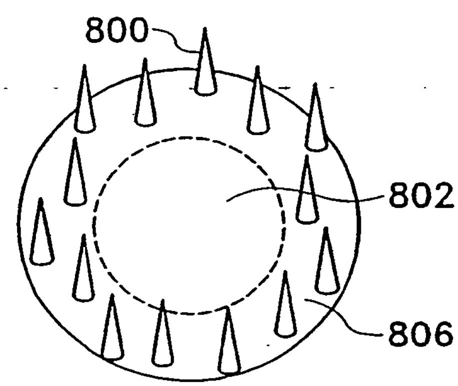


FIG. 8D

FIG. 9B

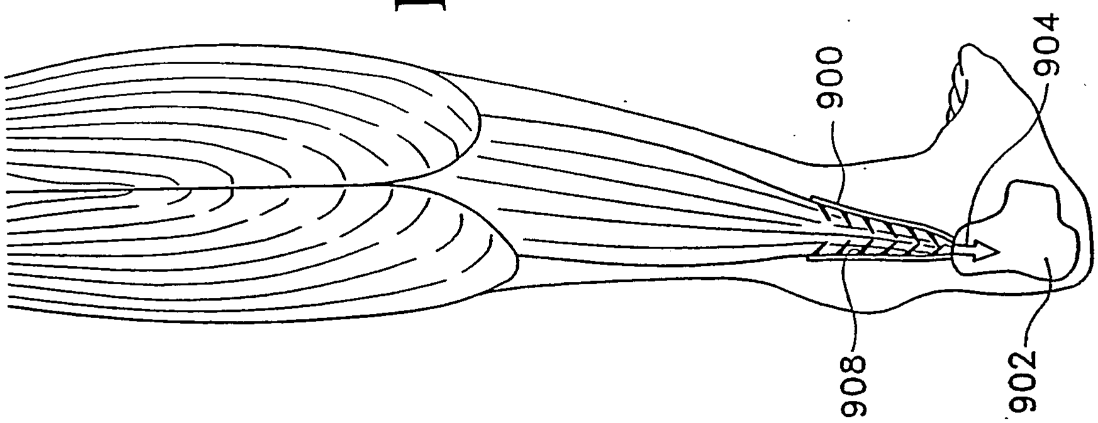
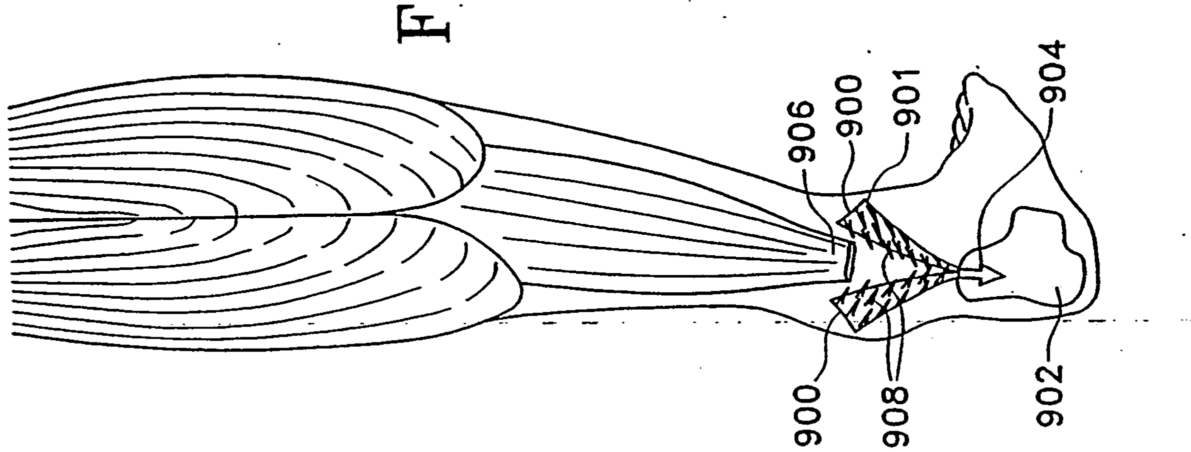


FIG. 9A



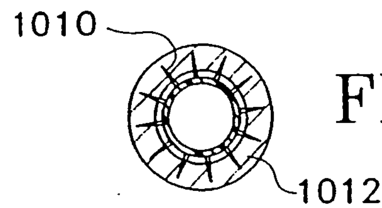


FIG. 10A

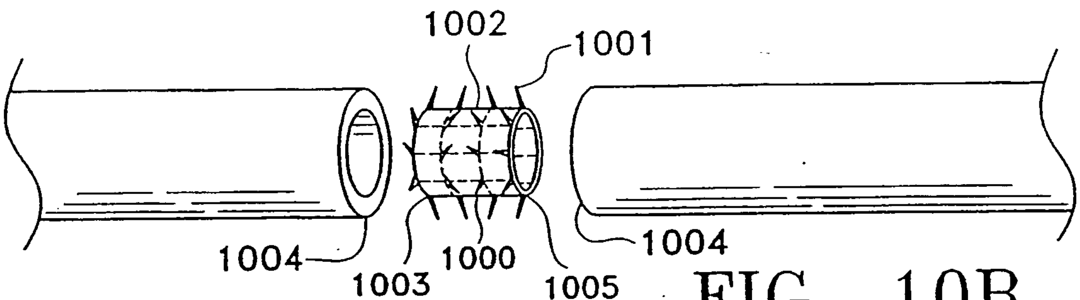


FIG. 10B

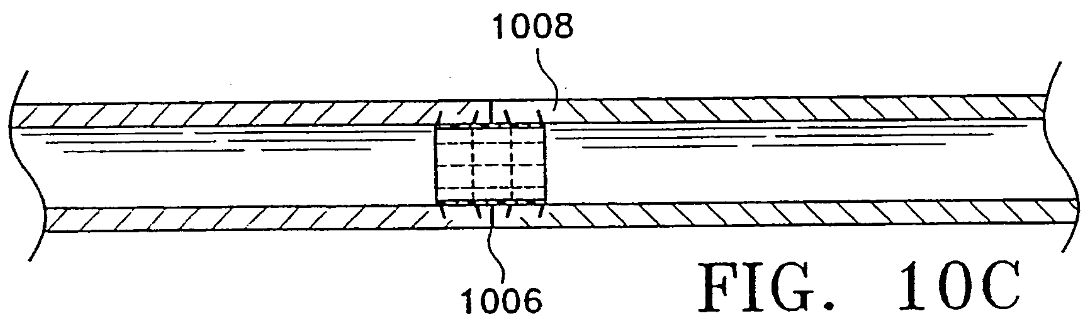


FIG. 10C

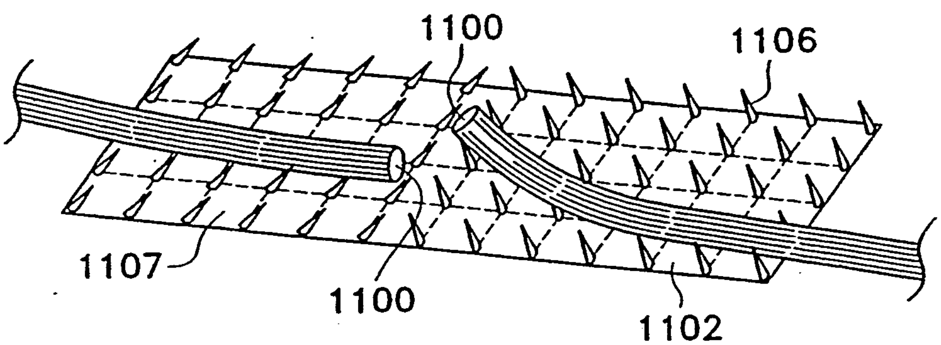


FIG. 11A

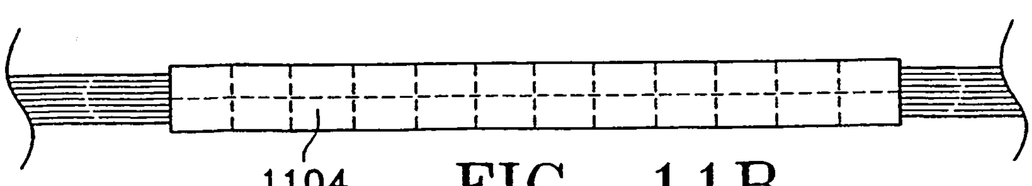


FIG. 11B

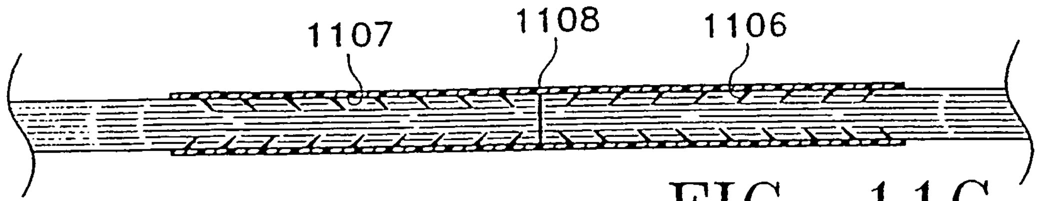


FIG. 11C

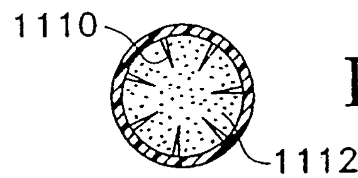


FIG. 11D

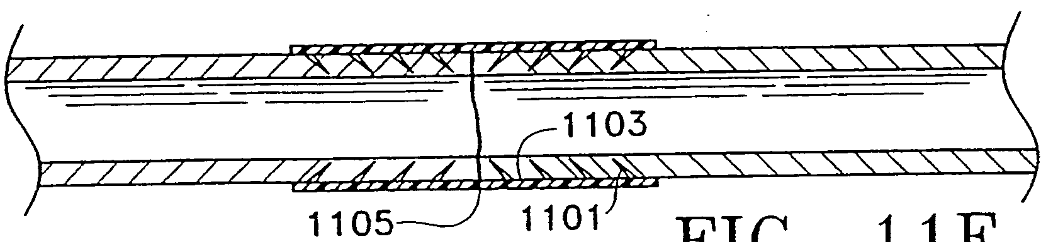


FIG. 11E

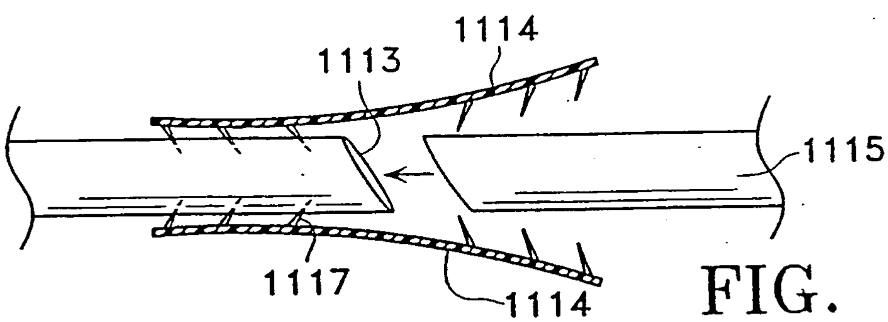


FIG. 11F

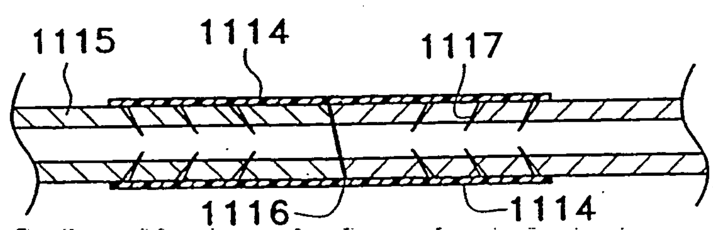


FIG. 11G

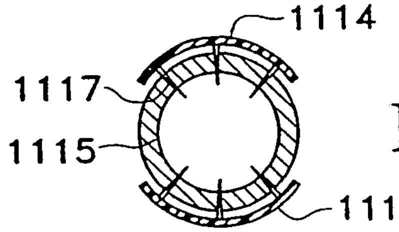
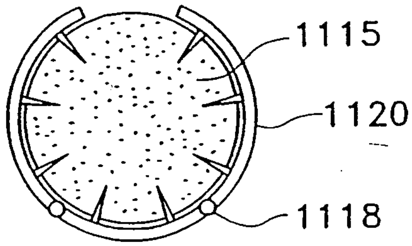


FIG. 11H

FIG. 11I



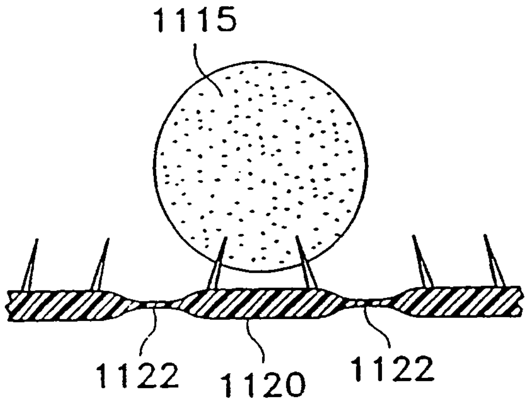


FIG. 11J

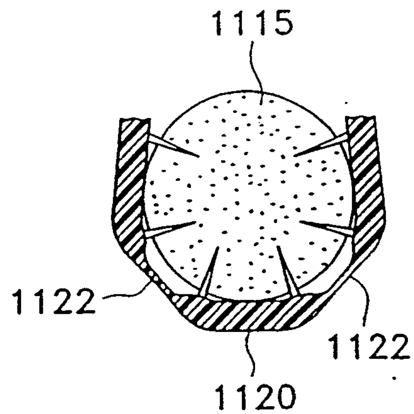


FIG. 11K

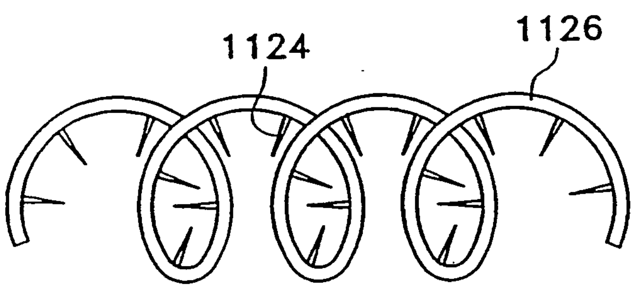


FIG. 11L

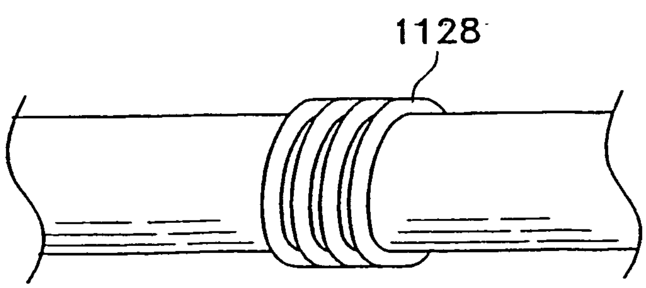


FIG. 11M

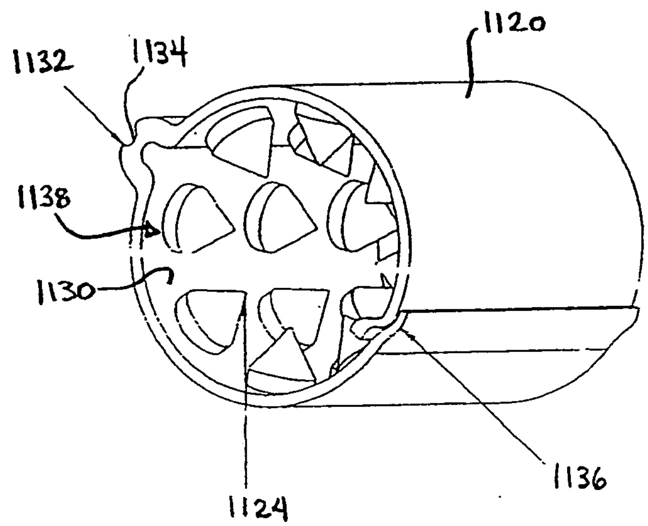


FIG. 11N

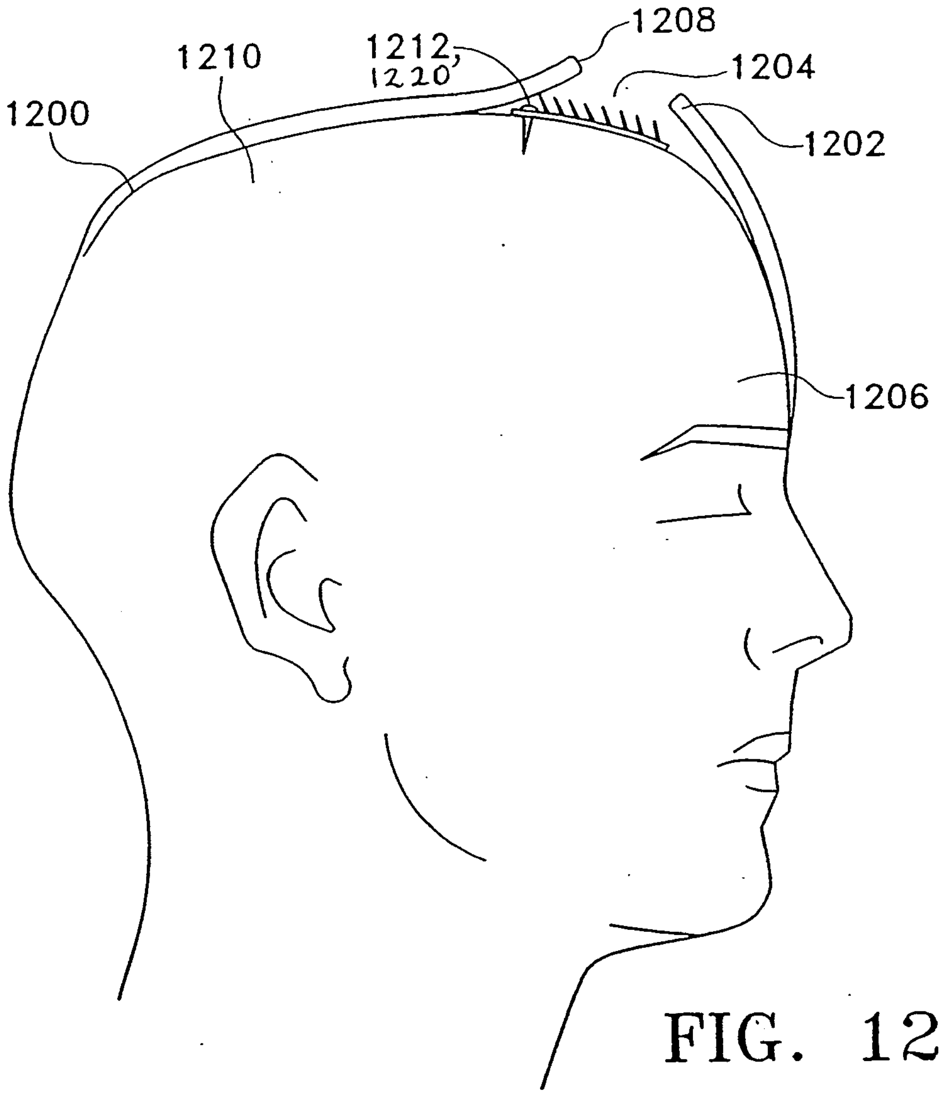


FIG. 12A

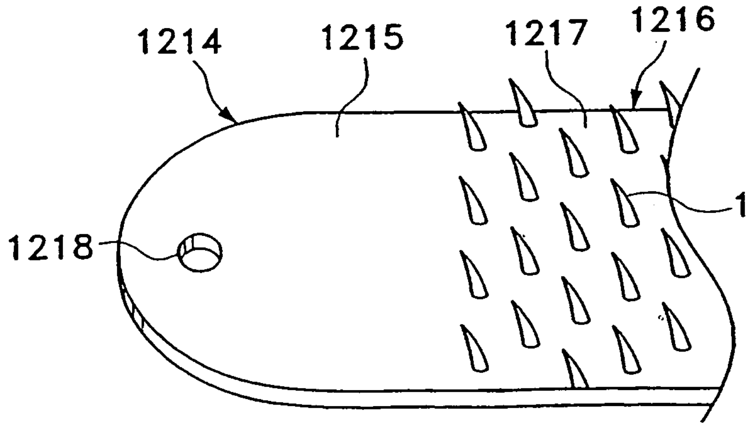


FIG. 12B